Appendix B
Laboratory Assessment

Appendix B, Laboratory Assessment

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1.0 Laboratory Assessment General Information

Clear, forthright, and effective communication between the assessment team and the laboratory is the foundation for a successful assessment. All participants shall strive to ensure that nothing hampers direct, timely communication between the laboratory and the assessment team.

The laboratory, Contractor or Navy may terminate the laboratory assessment if there is sufficient reason. Sufficient reason to terminate the process may include, but is not limited to, a change in project requirements, or a failure of the laboratory to meet the protocol requirements (i.e., time requirements, access requirements) of the Installation Restoration (IR) Quality Assurance (QA) Program as detailed in the Navy Installation Restoration Chemical Data Quality Manual (Navy IR CDQM).

From the time the assessment is announced through the completion of the assessment process, the lead assessor is the designated contact for the assessment team. At the direction or designation of the lead assessor, another member of the assessment team may serve as a secondary contact for the assessment team. At the initiation of the assessment process, the laboratory shall also designate primary and secondary contacts. Typically, the laboratory's primary contact is a representative from the QA staff, or a member of management.

When assessments are executed by the Naval Facilities Engineering Service Center (NFESC), oversight reviews shall be conducted by personnel other than those who conducted the review (i.e., peer review).

1.1 Objectives

Assessments serve as an independent and systematic investigation. In general terms, the objectives of these investigations are to determine if program participants are complying with applicable requirements (detailed in Appendix C), are technically capable of acceptably performing the specified types of analytical testing, and to determine if the laboratory's QA Program and systems are being effectively implemented and have systematic controls and procedures necessary to ensure continued acceptable performance.

1.2 Scope

This appendix describes the process and approach for laboratory assessments conducted in accordance with the Navy IR CDQM.

1.3 Roles and Responsibilities

Information on the roles and responsibilities of laboratories, the Navy, and Contractors can be found in the Navy IR CDQM.

1.3.1 Lead Assessors

The lead assessor is ultimately responsible for all phases of the assessment and has designated authority to make decisions regarding conduct of the assessment, assignment of team members, and activities involving members of the team.

The lead assessor:

- Represents the assessment team in discussions and communication with laboratory management
- Directs the preparation of the assessment report
- Authorizes the assessment report and follow-on corrective action correspondence by signature
- Facilitates daily briefs and the exit brief

1.3.2 Assessment Team Members

Assessment team members shall:

- Comply with the requirements of this manual
- Plan and carry out their assessment assignments in an effective manner
- Document all assessment activities in an appropriate manner
- Safeguard information in the assessment program files
- Verify the effectiveness of corrective actions taken in response to the assessment

1.3.3 Standards of Ethical Conduct

Each assessor must be familiar with standards of ethical conduct and submit a signed statement declaring freedom from conflict of interest as detailed in Appendix A.

1.4 Assessor Qualifications

Assessor qualifications must be submitted to the Engineering Field Division/Enginering Field Activity (EFD/EFA) for review and approval prior to conducting assessments. The assessors must be familiar with confidential business information (CBI) considerations as detailed in Attachment 1.

1.4.1 Education

Assessors shall possess a bachelor's degree in a scientific discipline, or have equivalent education and experience in laboratory assessment or related fields.

1.4.2 Training

Assessors shall have training in QA program assessment skills and techniques. Competence may be developed through orientation, training programs (e.g., those training programs offered by RAB, A2LA, ASQ, etc.), and on-the-job training.

All new assessors shall undergo a training period in which they work side-by-side with an experienced assessor for a minimum of four assessments or until the new candidate is judged proficient by NFESC and the EFD/EFA.

1.4.3 Knowledge

The assessor shall have detailed knowledge and understanding of the subject matter area(s) in which they conduct assessments of Navy IR QA requirements and the theory and application of current and technical issues, including the following:

- Federal and state regulations
- Techniques and procedures for assessing laboratory performance in accordance with ISO Guide 25, the on-site assessment checklists, and other applicable technical documents (e.g., ISO Guide 58)
- Laboratory record-keeping practices
- Laboratory data collection, reduction, analysis, and reporting techniques and requirements
- Analytical methods applicable to the fields of testing for which the laboratory is being assessed

1.4.4 Experience

Assessors shall be experienced professionals having relevant experience in an environmental laboratory in the areas they are reviewing.

1.4.5 Personal Attributes

Assessors should possess personal and professional attributes and characteristics that enable them to effectively and professionally perform their assessor duties. Assessors should:

- Be fair, adaptable to different personality styles, logical, firm and decisive
- Have good judgment and listening skills
- Demonstrate leadership, planning ability, and an ability to use investigative techniques
- Be detail oriented, have tenacity, and stay focused on scientific reason
- Clearly and effectively communicate in direct personal conversations with individuals that range from entry level technicians to senior members of management
- Discuss and present technical issues at a level commensurate with the disciplinary expertise of the individuals being interviewed
- Prepare written documents that describe and document assessment results and activities in a clear and impartial manner

- Have proven technical presentation skills that demonstrate the ability to successfully present, support, and defend a technical position

1.5 Lead Assessor

The lead assessor shall meet the assessor requirements identified above and, in addition, shall meet the requirements defined in the subsequent paragraphs.

1.5.1 Experience

Lead assessors shall have at least five years of relevant environmental laboratory experience.

1.5.2 Training

Lead assessors shall have relevant training in management skills.

2.0 Conducting Laboratory Assessments

This section presents the various protocols associated with a laboratory assessment. Flowcharts associated with these processes are provided at the end of this section.

2.1 Nomination

Contractors who plan to use a laboratory for Navy IR projects shall nominate the laboratory for assessment by forwarding a completed nomination form (Attachment 2) to the appropriate EFD/EFA.

The Contractor shall only nominate a laboratory for methods which the laboratory has satisfactorily demonstrated method performance in accordance with relevant Environmental Protection Agency (EPA) guidelines (40 CFR, Part 136, Appendix A). The Contractor shall request and review the information in the initial laboratory assessment package (Attachment 3) to substantiate the nomination. A copy of the documentation submitted by the laboratory shall accompany the nomination form submitted to the EFD/EFA.

2.2 Nomination Review

The EFD/EFA and NFESC will review the nomination, and determine the following:

- Whether or not an assessment of the laboratory is needed. Recent assessments conducted by other Department of Defense (DOD) agencies may be used as the basis for Navy acceptance and will be used if the scope of the assessments meet Navy IR Program and project requirements.
- Scope of services subject to review. The scope will establish whether the laboratory is being assessed for their capability to perform Contract Laboratory Program (CLP) methods, non-CLP methods, or a combination of methods. (A limited scope project assessment may be performed if the Navy currently accepts the laboratory for other methods.)
- Which agency will execute the assessment (i.e., the Contractor or NFESC).

2.3 Nomination Review Action

Within 14 calendar days of receiving the nomination form, the EFD/EFA will inform the Contractor and NFESC of the determinations made regarding the items presented in the bullets above.

2.3.1 Acceptance of Other DOD Agency Assessment Documentation

As previously stated, recent assessments conducted by other DOD agencies may be used as the basis for Navy acceptance and will be used if the scope of the

assessments meet Navy IR Program and project requirements. In these instances, the laboratory will be accepted for the period specified by the other agency. Upon acceptance, the laboratory shall participate in the on-going Proficiency Testing (PT) Program as described in Appendix D

2.3.2 Nomination Rejection

A laboratory nomination may be rejected if the information is incomplete or does not meet the requirements specified in this section or Appendix C. Rejected nomination packages will be returned to the Contractor without action. A letter issued by NFESC that summarizes the basis of the rejection will accompany the returned package.

2.3.3 Nomination Acceptance

If a laboratory nomination is accepted, an assessment in accordance with this manual shall be performed. The EFD/EFA will specify the agency that will be tasked with executing the assessment. The NFESC or Contractor chosen must then retain the services of assessors that meet the requirements of this manual. Assessor qualifications must be submitted to the EFD/EFA and NFESC for review and approval prior to conducting assessments. NFESC shall issue a letter advising the assessor of the approval, and maintain a central roster of approved assessors.

The following sections represent the protocol for conducting an assessment.

2.4 Initial Laboratory Assessment Package

The EFD/EFA authorizing the assessment shall forward a copy of the initial laboratory assessment package reviewed as part of the nomination process (Sections 2.1 and 2.2) to the NFESC or Contractor. This package will provide basic information needed by the assessors to initiate the assessment. The lead assessor (or the designated lead assessor) shall request any additional supporting information as required.

2.5 Areas of Review

The lead assessor shall assign areas of review to individual assessors. The reviews are performed to assess the laboratory's compliance with the requirements presented in Appendix C. Non-conformances identified as a result of the reviews will be documented in the laboratory assessment report as deficiencies (see Section 2.11 of this appendix). The assessors shall attempt to understand the nature of observed deficiencies (e.g., are they indicative of isolated individual problems, a lack of control systems, or a failure to effectively comply with existing systems). This effort is necessary so that the assessor can be in a position to evaluate the effectiveness of the laboratory's corrective action.

The scope of the assessment may influence whether certain elements are emphasized. However, the following sections present the various elements subject to review.

2.5.1 QA Program and Support Operations

The assessor responsible for review of support areas and the QA program shall at a minimum review the following general areas:

- Sample receiving, management, and custody control
- Data management (generation, reduction, reporting, review, and archival)
- Personnel training and qualification
- Method performance and validation
- QA Quality control (QC) program
- Document and record control
- Internal and external audits and proficiency assessments;
- Corrective action program
- Statistical QC
- Project management
- Laboratory equipment operation and maintenance
- Software QA: The scope of the software QA review element shall be tailored to reflect the scope of the laboratory's electronic data processing. As appropriate to the laboratory's capabilities, the review may address:
- Validation and continuing verification of software and data reporting spreadsheets
- Configuration control system for software versions and spreadsheets
- Documentation of data record changes

2.5.2 Methods

The assessment shall include the following as applicable to the method:

- Review of reference method SOPs
- Laboratory operations SOPs
- Record management system
- Procurement of items and services
- Initial demonstration and continuing demonstration of method performance certificates and supporting data
- Method performance data (method detection limits (MDLs), laboratory control samples (LCS), MS/MSD, and any other accuracy or precision data.)
- Proficiency testing results (if available)
- Data deliverable
- Interviews with analysts

The actual number and type of procedures subject to review will be commensurate with the services the laboratory provides or will provide to Navy. Additional methods and operations shall be reviewed as necessary to meet the scope of the evaluation as specified by the EFD/EFA authorizing the review.

2.5.2.1 CLP Methods

The primary objective of a CLP assessment is to determine if a laboratory has systems and practices in place to perform the documented version(s) of the statement of work (SOW) without deviation.

The assessors shall evaluate the laboratory's written instructional procedures (standard operating procedures (SOP)) to determine if execution of the procedures as written will comply with the SOW. The assessors shall also review bench-level practices and data records to determine which version(s) of the SOW is being used and documented by the laboratory. Inconsistencies between the SOW and the laboratory's procedures or practices shall be identified.

The majority of IR projects use SW-846 methods, CLP methods should only be reviewed if the project requires them.

2.5.2.2 Non-CLP Methods

Assessment of a laboratory's capability to acceptably perform non-CLP methods (e.g., SW-846 methods, Clean Water Act methods, Performance Based Measurement System (PBMS), or "specialty" methods and procedures[1]) requires a two step process:

- Review of the laboratory's SOPs (for technical adequacy)
- Determination of whether or not the laboratory's performance complies with the written policies and procedures, as evidenced by staff interviews and laboratory practices and records

PBMS[2] is a new proposal by the EPA to allow for more flexibility and technology innovation.

2.5.2.3 Organic

For organic methods and operations, the following, at a minimum, shall be reviewed:

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[1] Specialty methods are methods or procedures not considered routine in the environmental testing industry.

[2] PBMS is a set of processes wherein the data quality needs, mandates, or limitations of a program or project are specified, and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective manner.

- Gas Chromatograph (GC) volatile method(s)
- Gas Chromatography–Mass Spectrometer (GC-MS) volatile method(s)
- Organic sample preparation and clean-up method(s)
- GC semivolatile method(s)
- GC-MS semivolatile method(s)
- GC fuel hydrocarbon method(s) and
- High Performance Liquid Chromatography (HPLC) polynuclear aromatic hydrocarbon (PAH) method
- HPLC explosive method

2.5.2.4 Inorganic

For inorganic methods and operations, the following at a minimum shall be reviewed:

- Acid digestion of waters and soils
- Inductively Coupled Plasma (ICP) analysis of digestates
- Graphite Furnace Atomic Absorption (GFAA) analysis of digestates
- Inductively Coupled Plasma/Mass Spectrometry (ICP/MS) analysis of digestates (if performed)
- Preparation and analysis for determination of mercury
- Trace ICP
- High salinity sample handling

2.5.2.5 General Chemistry

For general chemistry methods and operations, the following at a minimum shall be reviewed:

- Distillation and analysis methods for determination of cyanide
- Preparation and analysis methods for determination of hexavalent chromium (if performed)
- Method(s) for determination of percent moisture or percent solids
- Method(s) for determination of oil and grease, or total recoverable hydrocarbons
- Leachate/Extraction methods (i.e., Toxicity Characteristics Leaching Procedure (TCLP))
- Method(s) for determination of water quality anions (Cl^-, NO_3^-)
- Method for determination of total organic carbon and total organic halides

2.5.2.6 Specialty

For "specialty" methods, the assessor shall review the procedures performed by analysts, and determine if the practices are compliant with laboratory SOPs, technically valid, appropriately documented, and are performed under the necessary systems and controls for the method. Examples of these types of "specialty" methods include:

- Radiochemistry
- National Oceanographic and Atmospheric Administration (NOAA) Status & Trends
- GC-MS low and high-resolution dioxin method(s) (if performed)
- Determination of alkyltins
- Analysis of biota
- Determination of contaminants at ultra-low trace levels
- Determination of high explosives

2.5.3 Project Documentation

In some circumstances a specific project may be associated with the laboratory assessment. Prior to initiation of on-site activities, the assessment team shall review a copy of the project documents (e.g., sampling and analysis plan, QA project plan) in order to assess the laboratory's capabilities to support the project. These documents shall also be reviewed to determine if actual laboratory practices and procedures conform to the project documents.

2.6 Pre-On-Site Review

The assessment team will identify significant deficiencies to the laboratory, and to the Contractor or NFESC in the form of an initial assessment recommendation letter, submitted within 14 calendar days of receiving the Initial Laboratory Assessment Package.

The letter shall also include a recommended course of action of either continuing or terminating the assessment process. The Contractor or NFESC shall forward a copy of the initial assessment recommendation letter to the EFD/EFA.

2.6.1 Continuation

If there are no significant deficiencies, the assessment will continue. Any deficiencies identified will be incorporated into the assessment report (Section 2.11). The laboratory shall address the deficiencies as a part of the corrective action phase (Section 2.13).

2.6.2 Termination

If the pre-on-site assessment indicates that the laboratory will not be able to meet Navy requirements, a summary of the issues shall be provided to the Contractor or NFESC. The summary shall be forwarded to the EFD/EFA, which will determine the appropriate course of action and notify the laboratory (via letter generated by NFESC). It is the responsibility of the Contractor to reinitiate the process if use of the laboratory is pursued.

2.7 Proficiency Testing (PT)

2.7.1 Historical PT

A review shall be conducted of the PT results from the past two years. Appendix D provides more information regarding this review.

2.7.2 Current PT

As part of the assessment process, a laboratory shall successfully analyze PT samples, which test proficiency, and are reflective of the methods the laboratory will use on Navy samples. The assessing organization is responsible for providing the laboratory with PT samples obtained from a PT provider that is compliant with the provisions of Appendix D.

2.8 On-Site Assessment Schedule

Unless an assessment is intended as an unannounced on-site assessment, the lead assessor shall provide the laboratory with an advance copy of the proposed schedule and agenda for the on-site assessment. The laboratory shall be afforded the opportunity to comment on the proposed agenda, to identify any likely conflicts, and to propose a revision that better accommodates site-specific operations. Unless a laboratory's proposed agenda changes will impede the assessment team's ability to successfully complete the assessment in a timely manner, every effort shall be made to accommodate the laboratory's suggested revisions.

2.9 On-Site Assessment

A checklist[3] is to be used as a tool for conducting laboratory on-site assessments. Assessors must exercise professional judgment to determine if additional information (not covered by the checklist) is required to provide a complete assessment of a laboratory.

Deficiencies identified during the on-site assessment shall be discussed with staff members at the time the deficiencies are identified. If the responsible personnel have questions regarding the basis for a deficiency, the assessor shall be prepared to explain

[3] Navy will develop a checklist upon finalization of Enclosure (1) to Appendix C.

the applicable requirement and the evidence that indicates that the requirement is not met. If laboratory personnel believe that a deficiency is not valid and they can provide supporting evidence for their position, such evidence shall be presented to the assessor for consideration. The evidence shall be presented when the deficiency is identified. The assessor shall take the evidence into consideration prior to noting the deficiency.

2.9.1 Safety Concerns

Assessors are required to comply with all applicable site-specific safety requirements, as defined by site management.

Laboratory practices that present safety concerns shall be presented to laboratory personnel at the time of observation and documented in the observation section of the assessment report.

2.9.2 Opening Meeting

The opening meeting serves as the initiation of on-site assessment activities. The laboratory's management is invited to participate to whatever extent they determine to be appropriate, but at a minimum, the laboratory's QA representative shall be present. The lead assessor conducts the opening meeting, and a list of attendees shall be generated for the assessment file. The objectives of the opening meeting are to:

- Introduce the assessment team members (and invited observers, as appropriate).
- Describe the scope, objectives, and approach for the assessment.
- Address the procedures related to confidential business information (CBI).
- Discuss any special safety procedures that the laboratory may think necessary for the protection of the assessment team. Under no circumstance is an assessment team required or allowed to sign any waiver of responsibility on the part of the laboratory for injuries incurred by a team member during an inspection to gain access to the facility.
- Confirm that the proposed agenda is acceptable, or negotiate revisions as necessary to accommodate critical site operations.
- Provide direct clarification to address the laboratory's concerns or questions.

2.9.3 Laboratory Walk-Through

A brief tour of the laboratory will be conducted to provide the assessment team with a general orientation of areas subject to review, and to introduce the assessors to the operational staff.

2.9.4 Assessment

The assessment team will review and assess the laboratory's procedures (e.g., SOPs), systems, practices, and records related to the performance of environmental testing, and will observe and interview laboratory personnel

regarding their practices. This systems approach requires that the assessors be thoroughly familiar with the Navy's QA requirements, and with the requirements of the methods, since all the relevant technical criteria and requirements are not reiterated in questionnaire format.

The team should determine the laboratory's past, present, and future capabilities to perform testing of acceptable, known, and documented quality. The assessors shall examine or collect objective evidence as the basis for making determinations of compliance.

2.9.4.1 Staff Interviews

Detailed interviews with staff members who perform the procedures will enable the assessors to understand and assess activities not necessarily reflected in documents, and should occupy a majority of the assessment team's on-site time. Supervisory personnel are welcome to attend staff interviews but the assessors shall ensure that questions are directed to, and answered by, the operational level staff, without interruption by their supervisor.

During interviews, the assessors shall ask individual staff members to provide a detailed, step-by-step description of their duties in the area under review. The assessor shall ask the staff member to provide details, documentary evidence, or demonstrations for each step in the process. For example, if a staff member states that a parameter is checked on a routine basis, the assessor should ask to see documentary evidence of the practice. As appropriate to the subject area, the interviews shall address the use of the equipment and supplies, calculations performed, data and records generated, and the identification and resolution of problems. Deficiencies identified during the interview process shall be discussed with the individual at a level commensurate with their responsibilities.

The interview process can be perceived as unpleasant or threatening. To mitigate this situation, the assessors shall adapt their interview style to the individual, without sacrificing the importance of the interview process.

2.9.4.2 Methods Review

A review of a laboratory's capability to perform a method shall be conducted in accordance with Section 2.5.2.

2.9.4.3 Records Review

The assessment team will review and assess laboratory records to determine if these materials are accurate, complete, internally consistent, and compliant with Navy requirements. The assessment team will also assess the laboratory's systems and procedures to ensure that after-the-fact reconstruction of the entire analytical process is possible.

Records subject to on-site review and assessment include, but are not limited to:

- Instrument run logs
- Instrument maintenance logs
- Standard material preparation and use records
- Reagent preparation records
- SOPs
- Procedures for the make-up and calibration of stock solutions and standard reagents
- Origins, purities, assays and expiration dates of primary standards, analytical reagents, and standard reference materials
- Method validation data
- Initial and continuing demonstration of method performance data
- Method detection limit and instrument detection limit data
- Records associated with the methods used to estimate precision and accuracy in general, and for specific analysis
- Analyst training and qualification records
- Proficiency test results
- Assessment reports and corrective action documentation for:
    - Previous assessments
    - Internal assessments and management reviews
- Deficiency tracking records
- Corrective action reports
- Statistical control data
- Precision and accuracy data
- Sample receipt and handling records
- Sample custody records
- QA reports
- Calibration records for instruments, methods, and equipment

2.9.4.4 Data Package Review

The assessment team selects and conducts a brief review of at least one fully validatable data package from each analytical functional area. The data packages shall have been produced within the previous year, using the laboratory's current data reduction and reporting systems. The purpose of this review is to determine if the laboratory's data reporting systems are complete and effectively implemented, and are capable of producing a data package that allows after-the-fact reconstruction of the entire analytical process.

Whenever possible, the data deliverables reviewed during the assessment shall be selected from recent Navy sample data or other DOD clients. If recent DOD data deliverables are not available, the assessment team, in consultation with the laboratory QA officer, may select a fully validatable data deliverable from another source.

2.9.4.5 Quality Assurance Program and Operations

The assessment team reviews and assesses the content and implementation of selected non-analytical procedures. The purpose of this assessment is to determine whether the laboratory's procedures:

- Provide for complete, accurate, and acceptable implementation of the laboratory's QA program
- Comply with Navy's QA requirements
- Are effectively and accurately implemented by the laboratory staff

Examples of procedures that are routinely subject to review include the laboratory's procedures for document control, statistical control, determination and use of method detection limits, internal assessments, and personnel qualification.

2.9.4.6 Laboratory Information Management System (LIMS)

The assessment team shall review the content and implementation of the laboratory's software QA plan. The purpose of the review is analogous to the information provided in Section 2.9.4.5.

2.9.4.7 Daily Debrief

At the conclusion of each day of an on-site assessment, the lead assessor will conduct a debrief meeting for the assessment team and the laboratory. Debriefs are open to all laboratory representatives, at management's discretion. The purpose of the daily debrief is to provide an informal presentation of assessment findings and give the laboratory an opportunity to request or provide additional information.

2.9.5 Documentation of Assessment Activities

The correspondence, records, documents, copies, and all supporting information that is generated, obtained, compiled, or reviewed during the assessment process shall be managed and maintained in the assessment files. The records must allow after-the-fact reconstruction of the overall assessment process from planning the assessment scope through final resolution of deficiencies based on corrective action documentation.

These files shall be forwarded by the assessment organization to the Contractor or NFESC when an assessment recommendation is made. The Contractor or NFESC shall maintain the files as specified by the EFD/EFA, and make them available to the EFD/EFA upon request.

Members of the assessment team are responsible for keeping complete and accurate records of all assessment activities. Each assessing organization shall issue their assessors a controlled notebook for the purpose of recording observations and notes. The assessment notebooks shall be used to record all relevant information and observations during an on-site assessment. Unused spaces shall be lined out, as practical. The assessment notebooks shall be completed as official records and written legibly in ink.

Assessors that conduct interviews shall document the following:

- Participant(s)
- Subject(s) discussed
- Area(s) reviewed
- Method(s) reviewed
- Results, conclusions, or observations noted during the interview

Assessors that review laboratory methods, data, documents, or records shall document:

- Type of records reviewed
- Deficiencies, including the specific record(s) that were the basis for the deficiency. As appropriate to the nature of the deficiency, the assessor shall request or make a copy of the relevant material.

Assessors' observations of laboratory operations, practices, or conditions that may be identified as deficiencies shall be documented in the assessment notebook. The notebook shall also be used to document observations that may merit the attention of organization or project management.

2.9.6 Exit Brief

Upon conclusion of the on-site assessment, the lead assessor will conduct an exit brief to provide the laboratory with informal information regarding the assessment. The assessors shall inform the laboratory of all categories of on-site assessment deficiencies and observations and provide the laboratory with a written list of these findings. This list shall be used as the basis for the on-site assessment section of the assessment report, new categories of on-site deficiencies may only be added with the consent of the EFD/EFA, and discussion with the laboratory. However, deficiencies resulting from other phases of the assessment

(i.e., PT and pre-on-site assessment phases) may be added to the final assessment report.

In addition, the lead assessor will provide a description of the schedule and objectives of the final assessment report, corrective action phase, and final assessment status.

The lead assessor will also provide the laboratory with a questionnaire (Attachment 4) that solicits feedback regarding assessor performance. The questionnaire should be forwarded to NFESC in the stamped, addressed envelope provided with the questionnaire. NFESC will forward a copy of the completed questionnaire to the Contractor upon closure of the assessment. The Contractor will provide the feedback to the assessing organization as a resource for evaluating and improving assessor performance.

2.10 Team Self-Assessment

At the conclusion of each laboratory assessment, the lead assessor will hold an informal "lessons learned" meeting with assessment team members. A Navy representative may elect to participate. The assessment team will review the overall assessment, and attempt to identify and define any problems or issues that relate to the assessment process or the assessors' performance. During this continuous quality improvement process, the emphasis will be on determining whether assessment team corrective actions are warranted. The level of effort required for this self-assessment is at the discretion of the organization, or as directed by the Contractor or NFESC.

If the assessment team included a new assessor fulfilling training requirements, the senior assessors on the team shall submit an evaluation of his or her performance to the EFD/EFA and NFESC, which will be used to determine proficiency.

2.11 Assessment Report

An assessment report shall be generated by the assessors upon completion of the on-site assessment. The final assessment report shall be issued to the laboratory within 14 calendar days of completion of the on-site assessment.

2.11.1 Objectives

The primary objective of the assessment report is to document the results of the assessment, and provide the laboratory with the information necessary to address and resolve all deficiencies.

2.11.2 Format

Attachment 5 contains an example assessment report. The report represents an acceptable format that should be used as a template to provide a consistent means of documenting assessment results and conclusions.

2.11.3 Content

2.11.3.1 General Information

The assessment report is signed and distributed by the lead assessor and shall include the following information as appropriate to the individual assessment:

- Date(s) and location(s) of the assessment.
- Identification of assessment team members and observers.
- Identification of opening and exit brief meeting participants.
- Identification of persons contacted during assessment (by name or title).
- Description of each deficiency.
- Due date(s) and required response(s) from the laboratory.

2.11.3.2 Deficiencies

Deficiencies identify those activities, practices, or procedures that represent a departure from Navy requirements or that threaten the quality, technical defensibility, or project acceptance of Navy data.

A description of each deficiency shall be provided in sufficient detail so that it is clearly understood by the laboratory. In addition, the basis for each deficiency (e.g., reference method section, CFR citation, or Navy IR CDQM) shall be stated or referenced.

Some deficiencies may be identified although the laboratory has an appropriate and acceptable policy and procedure that addresses the issue. In this case, the laboratory's system is acceptable, but the implementation of the system is not. The assessment report shall identify implementation deficiencies that are identified despite an acceptable quality system.

The assessment report shall identify systematic deficiencies, which are a result of incomplete or ineffective quality systems, and those that are a result of the laboratory's failure to comply with technical requirements.

2.11.3.3 Observations

The assessors shall note observations that reflect on the capabilities and capacity of the laboratory, but do not constitute deficiencies. Response from the laboratory is not required. As stated in Section 2.9.1, observations that present safety concerns shall be presented in this section.

2.11.4 Review and Approval

The lead assessor shall review and approve the final version of the assessment report to ensure that the report is complete, accurate, and conforms to the requirements of this manual.

2.11.5 Distribution

The assessment report is transmitted to the designated point of contact at the laboratory's organization, with a copy provided to the Contractor or NFESC. A laboratory that takes exception to one or more deficiencies may make an appeal as detailed in Section 2.20.

2.12 Voluntary Withdraw

A laboratory may choose to voluntarily withdraw from the evaluation process without prejudice. Upon receipt of written notice of withdrawal from the laboratory, the assessor will terminate the evaluation process and provide the Contractor or NFESC with notification that the evaluation process has been terminated.

2.13 Corrective Action Phase

Immediately upon receipt of the assessment report, the laboratory enters the corrective action phase of the assessment process, in which the laboratory implements corrective actions, and the assessment team assesses whether the laboratory has successfully closed the deficiencies.

2.13.1 Corrective Action Plan

Within 21 calendar days of receipt of the assessment report, the laboratory shall provide a written corrective action plan. The corrective action plan shall:

- Describe the planned corrective actions for resolution of deficiencies. The plan must provide sufficient detail to allow the assessment team to determine if the planned actions will successfully resolve the root cause of the deficiencies.
- Provide a proposed schedule for development and implementation of corrective actions (the completion schedule shall call for all of the corrective actions to be implemented within 60 calendar days from the date of receipt of the assessment report).

2.13.2 Assessment of Corrective Action Plan

The assessor shall supply a written assessment of the laboratory's corrective action plan within 14 calendar days of receipt of the plan. The written assessment shall notify the laboratory if any of the planned corrective actions are determined to be nonresponsive or would not successfully resolve the deficiency. The written assessment shall provide sufficient detail to ensure that the laboratory understands the deficiency, and why the corrective action was determined to be deficient.

Corrective actions must be resolved within 60 calendar days from the date of receipt of the assessment report.

A laboratory that takes exception to the decision(s) made during the corrective action phase may submit an appeal as detailed in Section 2.20.

2.13.3 Request for Extension of Corrective Action Phase

A written request for an extension to the corrective action phase of up to 21 calendar days may be submitted (to the lead assessor) by a laboratory as soon as the need is identified, but no later than 21 calendar days prior to the end of the corrective action phase. The lead assessor shall forward the request to the Contractor or NFESC who will determine if an extension will be granted (based on input from the EFD/EFA) and inform the lead assessor of the decision. The lead assessor shall then provide written notification to the laboratory.

2.13.4 Implementation and Documentation of Corrective Actions

During the corrective action phase, the laboratory shall implement corrective actions to resolve each of the deficiencies identified in the assessment report.

For example: If the corrective action required to resolve a deficiency was to revise an operating procedure, the laboratory shall complete the revision, issue controlled copies of the new procedure, train responsible personnel in the new provisions, and adopt use of the new version.

Within 60 calendar days from the date of first receipt of the assessment report, the laboratory shall supply documentation (to the assessment team), which provides demonstrable evidence that new policies, systems, controls, procedures, or practices have been implemented, and are now part of the laboratory's routine operation. Documentation that indicates that a new practice is proposed or planned, will not support closure of the associated deficiency.

2.13.5 Evaluation of Corrective Action Documentation

Upon receipt of the laboratory's documentation of corrective actions, the assessment team will review the documentation, and determine if it demonstrates that the deficiencies have been successfully resolved. A deficiency will be considered resolved if the root cause of the deficiency has been addressed, and documentation indicates that the laboratory has developed and implemented internally consistent policies, procedures, and practices that comply with Navy requirements. In some instances the first submittal by the laboratory may not satisfy these criterion. If this is the case, the lead assessor shall inform the laboratory (in writing within ten days of receipt of the documentation). If the laboratory is unable to provide sufficient documentation in their second submittal,

the assessor will notify the Contractor or NFESC, who in turn will advise the assessor if the assessment should be continued.

A laboratory that takes exception to the decision(s) made during the evaluation of corrective action phase may submit an appeal as detailed in Section 2.20.

2.14 Follow-Up Assessment

At the conclusion of the corrective action period, the assessment team may conduct a laboratory follow-up assessment. The follow-up assessment may be conducted on an announced or unannounced basis to satisfy a limited set of objectives in accordance with the provisions of this manual. Follow-up assessments shall be conducted with the concurrence of the EFD/EFA. If the follow-up assessment indicates that the laboratory has successfully implemented all required corrective actions, the assessment can be successfully closed. If the follow-up assessment indicates that deficiencies are still unresolved, they shall be resolved in order for the laboratory to successfully complete the assessment.

2.15 Assessment Recommendation

The assessment team shall determine the recommended assessment status of the laboratory within ten calendar days of the conclusion of the corrective action period, following review of the corrective action documentation submitted by the laboratory. The lead assessor shall prepare a letter that describes the recommended assessment status of the laboratory, to include the method(s) and matrix(ces) for which the laboratory is deemed acceptable to perform analyses, and the conclusions of the assessment team regarding the laboratory's ability to comply with all applicable requirements. This letter shall be distributed under the signature of the lead assessor to the laboratory and the Contractor or NFESC. The lead assessor shall also forward the original assessment files (i.e., correspondence, records, documents, copies, and supporting information that is generated, compiled, or reviewed during the assessment process) to the Contractor or NFESC as detailed in Section 2.9.5.

If a small percentage of deficiencies remain unresolved, the assessment team may determine that it is appropriate to document those cases where resolution is not demonstrated and distribute the assessment recommendation letter. This may only be done if the deficiencies will not impact Navy projects, and the corrective action response provides demonstrable evidence that the laboratory requires additional time in order to successfully close the deficiency.

If the final assessment status is determined to be unsuccessful, the report shall include a description of the unresolved deficiencies. It is the responsibility of the Contractor or NFESC to resolve the deficiencies before a laboratory may be proposed.

2.16 Laboratory Proposal

A laboratory may be proposed for Navy use upon successful completion of an assessment conducted in accordance with this manual. To propose a laboratory for Navy use, the Contractor or NFESC will submit the originals or certified copies of all documentation specified in Attachment 6 (Laboratory Proposal Package Checklist) to the appropriate EFD/EFA. Certified copies are those that have been verified by the sender as true copies of the original. Certification may be communicated via a memo that accompanies the documents sent. The EFD/EFA will review the package and forward the package to NFESC within ten calendar days with a letter of transmittal summarizing their evaluation of the package. NFESC will review the package to determine if the stated requirements have been met and collaborate with the EFD/EFA on the appropriate course of action. Within ten calendar days from receipt of the package from the EFD/EFA, NFESC will inform the laboratory of their decision. If the Navy determines that the requirements were not met, acceptance will be denied.

If the Navy determines that the requirements were met, a verification assessment may be conducted to confirm the results of the assessment. If the verification assessment confirms that the requirements are met, the laboratory is accepted. If the verification assessment demonstrates that requirements have not been met, the laboratory is denied acceptance.

NFESC shall maintain the files as specified by the EFD/EFA.

2.16.1 Acceptance

Once the EFD/EFA and NFESC determine that a laboratory has met the requirements of this appendix, the laboratory is accepted to perform analyses (on a method/matrix specific basis) under the IR Program Navywide for 24 months from the time the letter was issued. A letter of acceptance detailing which methods the laboratory is approved for shall be generated by NFESC and sent to the laboratory with a copy to the EFD/EFA and the Contractor.

2.16.1.1 Suspension

The Navy may suspend a laboratory's acceptance in total or in part for up to six months to allow time for the correction of deficiencies or areas of noncompliance. Reasons for suspension include, but are not limited to:

- Failure to successfully analyze and report PT samples pursuant to Navy requirements.
- Failure to submit an acceptable corrective action report, in response to a deficiency report and failure to implement corrective action(s) related to any deficiencies found during laboratory assessments within the required time period as required by Navy requirements.

- Failure to notify the Navy of any significant changes in the laboratory, as set forth in the Navy IR CDQM Section 1.1.4.

EFD/EFA shall determine whether to continue to use the laboratory on a case-by-case basis in consultation with NFESC. If the laboratory is unable to correct the deficiency within the time allotted, the laboratory's acceptance status shall be revoked in total or in part. A laboratory may appeal this decision as detailed in Section 2.20.

2.16.1.2 Revocation

The Navy may revoke a laboratory's acceptance status if the laboratory is not able to comply with this manual. Reasons for revocation of acceptance include, but are not limited to:

- Submittal of proficiency test sample results generated by another laboratory as its own.
- Misrepresentation of any material fact pertinent to receiving or maintaining acceptance.
- Denial of entry during normal business hours for an on-site assessment.
- Conviction of charges for the falsification of any report of or relating to a laboratory analysis.

After correcting the reason/cause for revocation, the laboratory may be reassessed. A laboratory may appeal this decision as detailed in Section 2.20.

2.17 Denial

If requirements have not been met the laboratory will not be accepted for use. NFESC will identify the issues that are deficient and forward this information to the Contractor or the laboratory (if NFESC is executing the assessment). It is the responsibility of the Contractor or NFESC to coordinate resolution of the issues identified, if the use of the laboratory is pursued. A laboratory may appeal this decision as detailed in the appeals Section 2.20.

2.18 Once Accepted

Once a laboratory is accepted for Navy use, the laboratory may perform analysis under the IR Program Navywide for 24 months from the time the letter was issued. Announced and unannounced assessments may be conducted with the written concurrence of the appropriate EFD/EFA.

2.19 Reassessment

NFESC will keep track of which EFDs/EFAs are using the laboratory. Six months prior to the end of the laboratory's acceptance period, NFESC (with input from the EFDs/EFAs) will determine the appropriate course of action to take concerning reassessment of the laboratory. NFESC will notify the laboratory in writing of the Navy's decision. The Navy may elect to let the laboratory's acceptance status lapse if there are no projects that require the laboratory's services.

2.19.1 Complete Reassessment

The Navy may require the laboratory to be reassessed in accordance with this appendix. The EFD/EFA, in collaboration with NFESC, will determine if a Contractor will be tasked with executing the assessment, or if NFESC will perform the assessment. The process will begin without the laboratory being nominated.

2.19.2 Document Review

The Navy may elect to perform a document review of the laboratory. NFESC will request and review specific documents from the laboratory such as:

- SOPs
- PT results
- Control charts
- Initial and continuing demonstration of method performance capability certificates
- Reports from internal and management reviews with the corresponding corrective action documentation
- MDLs for applicable methods
- Quality manual

Based on this review, and the laboratory’s recent performance, the Navy will determine if an on-site assessment is warranted or if the laboratory should be accepted for another 24 months. As part of the document review, NFESC may send the laboratory PT samples as part of the ongoing PT program, detailed in Appendix D.

2.19.3 On-Site Assessment

As part of the reassessment process, the Navy may elect to perform an on-site assessment to verify the information submitted as part of the document review, to assess areas of concern, or to verify that laboratory protocols continue to be implemented that effectively address findings presented in the original assessment.

2.20 Appeal of Decisions

A laboratory may appeal decisions made during the evaluation process. Sections 2.20.1 and 2.20.2 outline the procedures to appeal decisions made by assessors or the Navy. A laboratory must make an appeal in writing, within 14 days of receiving written notification of the decision. The laboratory's response shall identify the decision being appealed and the basis for taking exception to the decision. Unsupported conclusions and claims that are unsubstantiated by corroborating documentation will not provide sufficient evidence to support a successful appeal claim.

When an appeal claim is determined to be valid, the exception is immediately corrected by issuing a revised assessment report, evaluation, or letter. Unsubstantiated appeal claims will remain unchanged.

2.20.1 Assessor

Laboratories that take exception to decisions made by assessors (e.g., deficiencies in the assessment report, evaluation of the corrective action plan, or notification that a deficiency has not been successfully resolved) shall notify the lead assessor in writing.

Immediately upon receipt of an appeal claim, the lead assessor will notify and provide a copy of the appeal to the Contractor or NFESC. The Contractor or NFESC shall then notify the EFD/EFA. The lead assessor will review the laboratory's exception documentation and provide the Contractor or NFESC with a written assessment of the validity of the laboratory's claim within seven calendar days of receipt of the claim. The Contractor or NFESC shall forward a copy of appeal claim and supporting documentation to the EFD/EFA. As requested by the Contractor or NFESC, the laboratory and the assessment team members may provide additional information or participate in follow-on discussions.

The Contractor or NFESC shall collaborate with the EFD/EFA to determine the disposition of appeal claims. The final decision regarding disposition of appeal claims rests with the EFD/EFA. The Contractor or NFESC will inform the lead assessor of the outcome of the evaluation. The lead assessor will then notify the laboratory in writing and issue any required revisions with a copy to NFESC or the Contractor. A copy of all correspondence and communication logs regarding exception appeals will be maintained in the corresponding assessment file.

2.20.2 Navy

Laboratories that take exception to decisions made by NFESC and the EFD/EFA (e.g., decisions to suspend, revoke, or deny acceptance) may make an appeal to the Naval Facilities Engineering Command (NAVFACENGCOM).

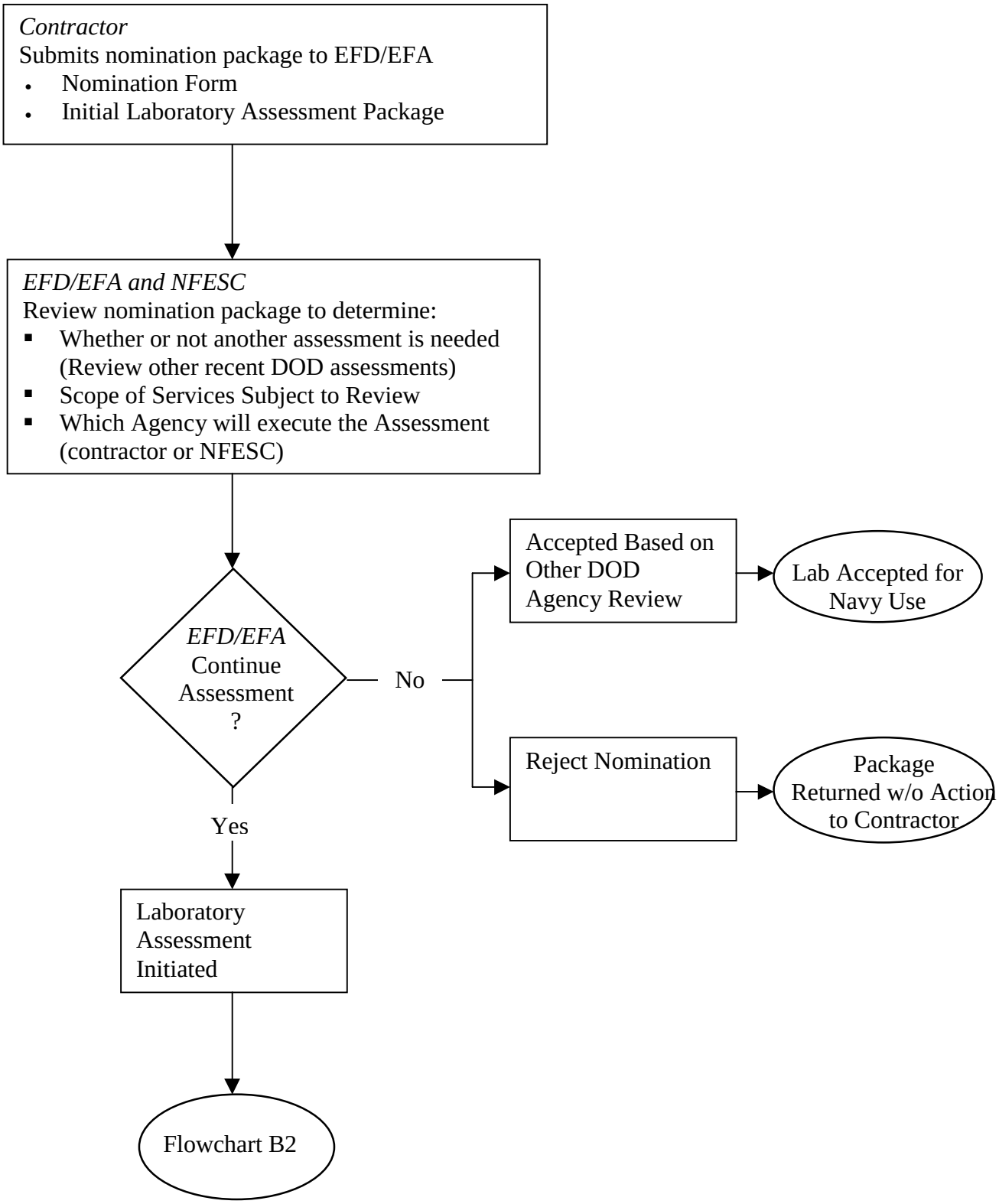
NAVFACENGCOM will review the laboratory's appeal claim and assess whether it is valid and substantiated, within 30 calendar days of receipt of the appeal. As requested by NAVFACENGCOM, the laboratory, Navy, Contractor, and assessment team members shall provide additional information or participate in discussions. The final decision regarding the disposition of appeal claims rests with NAVFACENGCOM.

When the appeal claim has been evaluated, NAVFACENGCOM will inform the laboratory, NFESC, and other interested parties of the decision via a letter. A copy of all correspondence regarding the appeal will be forwarded by NAVFACENGCOM to NFESC. NFESC will maintain this information in the corresponding laboratory file.

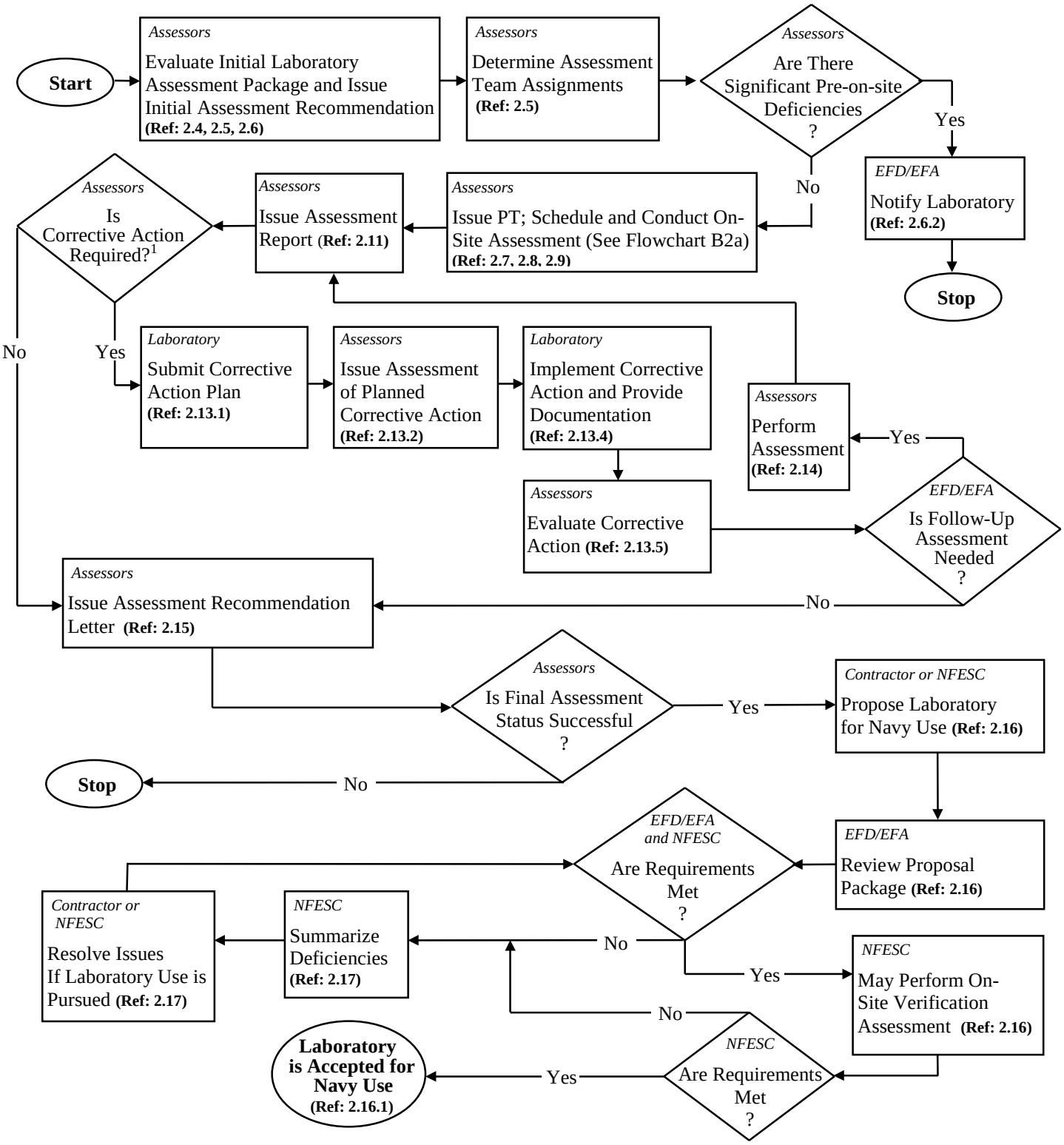
Appeals should be sent to:

Commander
NAVFACENGCOM
Washington Navy Yard
1322 Patterson Ave SE STE 1000
Washington, DC 20374-5065

Flowchart B1:
Laboratory Assessment General Overview



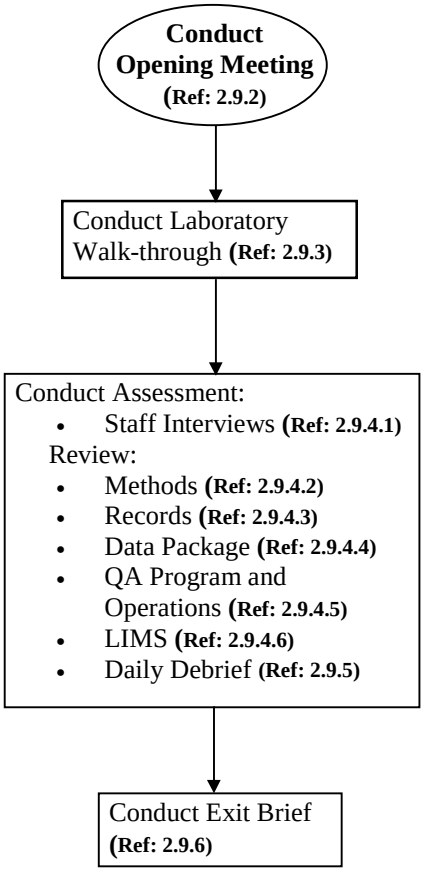
Flowchart B-2:
Laboratory Assessment Procedure Flowchart



Note: The process may be terminated at anytime by the contractor, Navy, or the laboratory. (Ref 1.0)

[1] If the laboratory decides to appeal any deficiencies noted in the assessment report, they must do so within 14 calendar days. (Ref: 2.20)

Flowchart B2a:
Laboratory On-Site Assessment Procedure



Note 1: A daily debrief will be conducted at the conclusion of each day during the on-site assessment (Ref: 2.9.4.7).

Note 2: Each member of the assessment is responsible for keeping complete and accurate records of all assessment activities (Ref: 2.9.5).

Appendix B
Attachment 1
Confidential Business Information

1.0 Purpose

This attachment details confidential business information (CBI) considerations of the Navy Installation Restoration (IR) Program.

During the assessment process, assessors may come into possession of information claimed as business confidential by the laboratory. The laboratory may protect this information from public disclosure under the Freedom of Information Act (FOIA) by declaring the information business confidential.

2.0 Protocol

During the opening meeting, the lead assessor shall provide Enclosure (1) to the appropriate laboratory management and answer any questions the laboratory management may have concerning CBI.

2.1 Making a CBI Claim

Information may be claimed as business confidential during the on-site assessment by the responsible laboratory official in one of two ways:

- Marking each item (e.g., each page, file, or sample) that is claimed as business confidential as “confidential business information,” “trade secret,” “proprietary,” or some other suitable phrase prior to the close of the on-site assessment.
- Submittal of the "Assessment Confidentiality Notice" form provided as Enclosure (2).

CBI may be purged of references to client identity by the responsible laboratory official prior to the conclusion of the on-site assessment. However, sample identifiers may not be obscured from the information.

After the on-site assessment, CBI claims may only be made by submitting the “Assessment Confidentiality Notice” to the appropriate agency as detailed below:

- If the laboratory has not completed the assessment process the claim shall be submitted to the Contractor or NFESC as appropriate.
- If the laboratory has been proposed to the Navy, the claim shall be submitted to NFESC.

The Navy is not responsible for disclosures made prior to receiving the claim.

2.2 Receiving a CBI Claim

Immediately upon receipt of the CBI claim, the receiving organization will:

- Take custody of the claimed items by listing them on a chain of custody sheet.

- Maintain controlled custody of the claimed information in all subsequent transfers of the information.
- Ensure that either each page is marked as “business confidential” by the laboratory or that a copy of the Assessment Confidentiality Notice is used as a cover sheet on claimed items.

Information claimed as CBI shall be held in a secure manner throughout the holding period of the assessment records and may not be reproduced or distributed inconsistently with 40 CFR Part 2.

If a CBI claim is received after the on-site assessment, the appropriate organization (i.e., assessment organization, Contractor, EFD/EFA, or NFESC) shall expedite the claim as soon as it is received, but the organization is not responsible for previous disclosures. The organization shall make efforts to associate the late claim with copies of the previously submitted information in its files.

3.0 Determining the Validity of a CBI Claim

NFESC (with input from the EFD/EFA) shall determine the validity of the CBI claim, in accordance with federal and state law. The following criteria will be used to judge the validity of the laboratory's claim:

- Measures taken by the laboratory to protect the confidentiality of the information, and the intent to continue such measures.
- Access to the information is not, and has not been, reasonably obtainable without the laboratory’s consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on showing of special need in a judicial or quasi-judicial proceeding).
- Availability of the information from public sources.
- Disclosure of the information would cause substantial harm to the laboratory’s competitive position.

If the Navy questions the claim that certain information is CBI, the laboratory will be contacted in writing and given 21 calendar days to exercise one (or more) of the following options:

- Provide justification of their claim to CBI
- Remove the claim of CBI
- Resolve the issue in a manner agreeable to both the laboratory and the Navy
- Engage legal assistance
- Appeal the action to NAVFACENGCOM
- Withdraw without prejudice from the evaluation process

Appendix B
Attachment 1
Enclosure 1
Navy Installation Restoration Program
Assessment Confidentiality Notice-
To Assert a Confidentiality Business Information Claim

NAVY INSTALLATION RESTORATION PROGRAM

ASSESSMENT CONFIDENTIALITY NOTICE

LABORATORY NAME	ASSESSOR NAME
LABORATORY ADDRESS	ASSESSOR ADDRESS
CHIEF EXECUTIVE OFFICER NAME	TITLE

TO ASSERT A CONFIDENTIALITY BUSINESS INFORMATION CLAIM

It is possible that the Navy will receive public requests for release of the information obtained during assessment of the facility above. Such requests will be handled by the Navy in accordance with provisions of the Freedom of Information Act (FOIA), 5 USC 552 and as defined in the Navy IR CDQM, Attachment 1 of Appendix B. The Navy is required to make assessment data available in response to FOIA requests unless the Navy determines that the data contain information entitled to confidential treatment or may be withheld from release under other exceptions to FOIA.

Any or all information collected during the assessment may be claimed confidential if it relates to trade secrets or commercial or financial matters that you consider to be confidential business information. If you assert a CBI claim, the Navy will disclose the information only to the extent, and by means of the procedures set forth in the regulations and guidelines (cited above) governing the Navy's treatment of confidential business information. The regulations require that the Navy notify you in advance of publicly disclosing any information you have claimed as confidential business information.

A confidential business information (CBI) claim may be asserted at any time. You may assert a CBI claim prior to, during, or after the information is collected. The declaration form was developed to assist you in asserting a CBI claim. It is not necessary for you to use this form. If it is more convenient, you may assert a CBI claim by marking the individual documents or samples "confidential business information." The assessor will be glad to answer any questions you may have regarding the Navy's CBI procedures.

While you may claim any collected information or sample as confidential business information, such claims are unlikely to be upheld if they are challenged unless the information meets the following criteria:

1. Your company has taken measures to protect the confidentiality of the information, and it intends to continue to take such measures.

2. The information is not, and has not been, reasonably obtainable without your company's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on showing of special need in a judicial or quasi-judicial proceeding).

3. The information is not publicly available elsewhere.

4. Disclosure of the information would cause substantial harm to you company's competitive position.

At the completion of the assessment, you will be given a receipt for all documents, samples, and other materials collected. At that time, you may make claims that some or all of the information is confidential business information.

If your are not authorized by your company to assert a CBI claim, this notice will be sent by certified mail, along with the receipt for documents, samples, and other materials to the Chief Executive Officer of your firm within 2 days of this date. The Chief Executive Officer must return a statement specifying any information that should receive confidential treatment.

The statement from the Chief Executive Officer should be addressed to (assessor, enter assessment organization address here):

Send registered mail, return-receipt requested within 7 calendar days of receipt of this notice. Claims may be made any time after the assessment but assessment data will not be entered into the special security system for confidential business information until an official confidentiality claim is made. The data will be handled under the agency's routine security system unless and until a claim is made.

TO BE COMPLETED BY FACILITY OFFICIAL RECEIVING THIS NOTICE: I have received and read this notice.	If there is no one on the premises of the facility who is authorized to make business confidentiality claims for the firm, a copy of this Notice and other assessment materials will be sent to the company's chief executive officer. If there is another company official who should also receive this information, please designate below.
SIGNATURE	NAME
NAME	TITLE
TITLE DATE SIGNED	ADDRESS

Appendix B
Attachment 1
Enclosure 2
Navy Installation Restoration Program
Assessment Confidentiality Notice-
Information Designated as Confidential

NAVY INSTALLATION RESTORATION PROGRAM ASSESSMENT CONFIDENTIALITY NOTICE	
LABORATORY NAME	Date
LABORATORY ADDRESS	
ASSESSOR NAME	CHIEF EXECUTIVE OFFICER NAME
ASSESSOR ADDRESS	TITLE

INFORMATION DESIGNATED AS CONFIDENTIAL	
No.	DESCRIPTION

ACKNOWLEDGMENT BY CLAIMANT

The undersigned acknowledges that the information described above is designated as Confidential Business Information as defined in the Navy IR CDQM, Attachment 1 of Appendix B. The undersigned further acknowledges that he/she is authorized to make such claims for his/her firm.

The undersigned understands that challenges to confidentiality claims may be made, and that claims are not likely to be upheld unless the information meets the following guidelines: (1) The company has taken measures to protect the confidentiality of the information and it intends to continue to take such measures; (2) The information is not, and has not been reasonably attainable without the company's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding); (3) The information is not publicly available elsewhere; and (4) Disclosure of the information would cause substantial harm to the company's competitive position.

TO BE COMPLETED BY FACILITY OFFICIAL RECEIVING THIS NOTICE I have received and read this notice (signature):	If there is no one on the premises of the facility who is authorized to make business confidentiality claims for the firm, a copy of this Notice and other assessment materials will be sent to the company's chief executive officer. If there is another company official who should also receive this information, please designate below.
ASSESSOR'S SIGNATURE	NAME
NAME	TITLE
TITLE DATE	ADDRESS

Appendix B

Attachment 2
Laboratory Nomination Form

Navy Installation Restoration Laboratory Nomination Form

Nominating Contractor Information:

Name: _____

Street Address: _____

_____

_____

Name of Contact: _____

Position and Title: _____

Phone Number: _____ Fax Number: _____

Type of Contract: ☐ RAC ☐ CLEAN ☐ Other: _____

EFD/EFA Associated With Contract:
☐ NORTHDIV ☐ EFA NORTHWEST ☐ PACDIV
☐ SOUTHDIV ☐ SOUTHWESTDIV ☐ EFA WEST
☐ EFA CHESAPEAKE ☐ LANTDIV

Laboratory Information:

Full Legal Name: _____

Street Address: _____

_____

_____

Name of Contact: _____

Position and Title: _____

Phone Number: _____ Fax Number: _____

Methods that the Contractor is nominating the laboratory to perform[1]:

☐ SW846 ☐ CLP ☐ Other: _____

Below are types common to Navy:

Type	Matrix		Method (Latest Version of):
	Soil/ Sediment	Water	
VOC (8260)			8260
VOC (8021)			8021
BNA			8270
PCB			8082
Metals(23 metals)			6010/7000
Pest			8081
TPH*			8015

* SOP and lab practices will be reviewed during assessment. because a PT from USACE is not available. The lab shall have State certification or shall have successfully analyzed a private PT provider PT sample in the last six months.

Provide additional types below:

Type	Matrix		Method (Latest Version of):
	Soil/ Sediment	Water	

[1] The laboratory shall be nominated for methods for which the Contractor has confidence in the laboratory's ability to demonstrate satisfactory method performance in accordance with relevant EPA guidance.

Appendix B
Attachment 3
Initial Laboratory Assessment Package Requirements

Initial Laboratory Assessment Package Requirements

Laboratories that have been nominated to provide analytical support for Navy Installation Restoration (IR) or Base Realignment and Closure (BRAC) environmental programs shall supply the items listed below to the assessment organization. The assessors will use the information provided to make an initial assessment of the laboratory's capabilities to support IR and BRAC environmental projects.

Initial laboratory assessment package items shall be compiled/submitted in the following order:

1. *Navy Installation Restoration Laboratory Information Sheet*: Enclosure (1)
2. *Organization Chart*: An organization chart depicting the lines of authority for laboratory positions, with identification of individuals for key positions including:
   - Lab Director
   - Quality Manager
   - Quality Assurance (QA) Officer
   - Operations Manager
   - Inorganic Section Supervisor
   - Organic Section Supervisor
   - Classical Section Supervisor
   - LIMS Systems Manager
   - Data Reporting Section Supervisor
   - Sample Management Supervisor
3. *Resumes*: Resumes for the individuals in key positions, including those identified in number 2 above.
4. *Laboratory Facility(ies) Floor Plan*: A floor plan of the laboratory facility(ies) with general production areas identified including:
   - Organic and inorganic sample preparation laboratories
   - Inorganic instrument laboratories
   - Volatile organic instrument laboratories
   - Semi volatile organic instrument laboratories
5. *List of Major Analytical Instrumentation*: A list of major analytical instrumentation (limited to those instruments that are routinely applied to production analyses).
6. *Completed Laboratory Compliance Checklist*: The laboratory shall complete this checklist, Enclosure (2), to demonstrate its compliance with Navy requirements (detailed in IR CDQM Appendix C[1]). More information may be provided on additional sheets of paper as needed. The checklist is available electronically from the Navy QA contact. This checklist is based on the DOD QS document.
7. *Quality Manual:* The laboratory's current document(s) that describe the laboratory's QA program, typically called the QA manual, QA program plan, or QA plan.
8. *Methods Information*: A list of methods (by EPA or other method reference as appropriate) routinely performed by the laboratory, with the applicable matrices specified. The laboratory must include initial demonstration of method performance certificates as detailed in

[1] This checklist will be generated upon finalization of Appendix C.

Appendix C (Laboratory Requirements Appendix) and MDLs for applicable methods. Supporting data and documentation does not need to be included.

9. *SOPs*: A list of titles of the laboratory's currently approved standard operating procedures (SOPs), with SOP number, revision number, and date of approval. As applicable to the assessment, the laboratory shall submit at least one SOP associated with each of the following categories:

   - Organics
   - Inorganics
   - General Chemistry
   - Radiochemistry
   - QA Program and Operations

   Note: The laboratory shall compile a complete set of all applicable SOPs for assessor review. The assessors may also request additional specific SOPs.

10. *Proficiency Testing*: Copies of the results (including corrective actions as appropriate) from nationally recognized PT programs completed during the last two years, including as appropriate: EPA CLP Quarterly Blinds; EPA EMSL-LV Radiochemistry Intercomparison Program; and United States Army Corps of Engineers (USACE) PT Program; Air Force Center for Environmental Excellence (AFCEE) PT Program.

Navy Installation Restoration Laboratory Information Sheet

Legal Name of Laboratory: _____

Street Address: _____

_____

_____

Mailing Address: _____
(if different)

_____

_____

Fax Number: _____ Hours of Operation: _____

Name of Owner: _____

Owner Address: _____
(If different from above)

_____

_____

	Name	Phone Number
Laboratory Director:		
Laboratory Quality Manager:		
Quality Assurance Officer:		

The undersigned persons understand and acknowledge that the laboratory will be assessed in accordance with the *Navy Installation Restoration Chemical Data Quality Manual*. The laboratory has received and reviewed this manual and is prepared to proceed.

The under-signed persons understand and acknowledge that the Navy or its Contractor will conduct an on-site assessment and may perform unannounced follow-up assessments.

I hereby certify that I am authorized to sign this form on behalf of the owner and that there are no misrepresentations in the information provided in the initial laboratory assessment package.

_____ _____
Signature of Quality Manager Date

_____ _____
Signature of Laboratory Director Date

Appendix B
Attachment 3
Enclosure 2
Laboratory Compliance Checklist

This checklist will be generated upon finalization of the Department of Defense Quality Systems Manual for Environmental Laboratories (Enclosure 1 to Appendix C)

Appendix B
Attachment 4
Assessor Evaluation Questionnaire

Please complete and return this form in the envelope provided. The feedback you provide will be used to evaluate and improve assessor performance. It will not affect the current assessment. Information provided on this questionnaire will not be communicated to the assessors until the laboratory completes the assessment process.

Assessor Name: _____
Laboratory Name: _____
Date of On-Site Assessment: _____
EFD/EFA Lab Will be Proposed to: _____

Please rank the assessor from 1 (low) to 5 (highest)

1.	Ability to communicate orally	1	2	3	4	5
2.	Ability to communicate in writing	1	2	3	4	5
3.	Ability to act objectively and fairly	1	2	3	4	5
4.	Ability to describe assessment results in a clear and impartial manner	1	2	3	4	5
5.	Ability to adapt to different personalities during interviews	1	2	3	4	5
6.	Professional characteristics	1	2	3	4	5
7.	Knowledge of :					
	a. Environmental laboratory methods	1	2	3	4	5
	b. Quality assurance issues	1	2	3	4	5

Overall Rank: 1 2 3 4 5

Please provide comments: _____

If there is no self addressed envelope provided, please return this form to NFESC:

Commanding Officer
Naval Facilities Engineering Service Center, Code 413/ Pati Moreno
1100 23rd Avenue
Port Hueneme, CA 93043-4370

Appendix B
Attachment 5
Example Assessment Report

ABC Auditors, Inc.
123 Central Ave.
New York, NY 99999
8 April 1998

Geo Labs
888 Pollo del Mar
Los Angeles, CA 99999

Subject: On-Site Assessment Report of Geo Labs, Los Angeles, CA

Dear Mr. Bond:
The attached report provides the results of the assessment of Geo Labs in Los Angeles, CA, preformed by ABC Auditors Inc., including information pertaining to the review of; laboratory preliminary documentation; Performance Testing (PT) information; and the on-site assessment.

As outlined in Appendix B of the *Navy Installation Restoration Chemical Data Quality Manual (IR CDQM)*, Geo Labs has 14 calendar days to submit a corrective action plan addressing the deficiencies identified in this report. For each finding, your response should include a discussion of the scope and approach for planned corrective actions, as well as a schedule for their implementation. The plan of action must provide sufficient detail to determine if the approach is technically reasonable. The completion schedule should call for all corrective actions to be completed within 60 calendar days of receipt of this report. Additional information pertaining to the procedures for responding to the enclosed assessment report can be found in IR CDQM, Appendix B, Section X.XX.

Your corrective action plan should be directed to my attention at the following address:

ABC Auditor, Inc.
123 Central Ave.
New York, NY 99999

I would like to express my appreciation to the members of the Geo Labs staff who were helpful and candid during our visit. Should you have any questions, or wish to discuss assessment deficiencies or proposed corrective actions, please contact me at (888) 888-8888, or call Ms. Elaine Eus at (888) 888-8888. Thank you for your attention.

Respectfully,

Gene Eric
ABC Auditor, Inc.

Attachment: Assessment Report

cc: G. Brooks/Acme Contracting

Assessment Report
of
Geo Labs
Los Angeles, CA

Requested by:
Acme Contracting

Prepared by:

ABC Auditor, Inc.
123 Central Ave.
New York, NY 99999

17 April 1998

1.0 Introduction

As requested by Acme Contracting, ABC Auditors, Inc. conducted an assessment of Geo Labs, Los Angeles, California. This audit process includes three primary phases: 1) Review of laboratory preliminary documentation; 2) Performance Testing (PT) review; 3) On-site assessment.

2.0 General Information

The laboratory assessment was initiated by the Commander, Midwest Division, Naval Facilities Engineering Command (COMMIDWESTDIV), and executed by ACME Contracting. ACME contracted with ABC Auditors, Inc., to conduct the assessment. Gene Eric and Elaine Eus were the assigned assessors, Gene Eric served as lead assessor. The assessment was structured as a general assessment to support Navy Installation Restoration (IR) projects.

Geo Labs has been providing commercial and government clients with routine environmental analysis services since 1982. Geo Labs has current work for Acme Contracting and XYZ Engineers. Geo Labs occupies three closely situated buildings, totaling 17,000 square feet. Copies of floor plans supplied by the laboratory are provided as Appendix A. At present, the laboratory has the ability to operate with multiple shifts during the week, and day shifts on the weekend.

3.0 Laboratory Preliminary Documentation Review

A review of laboratory supplied documentation was conducted. Documentation included the laboratory's quality assurance (QA) manual, selected standard operating procedures (SOPs) and SOP master list (Appendix B), list of major analytical instrumentation (Appendix C), and historical PT information.

The documentation was reflective of a laboratory that was prepared for the Navy's evaluation, as documented in ABC Auditor, Inc. initial assessment letter dated 16 Mar 98. Deficiencies associated with this documentation are found in Section 6.0 of this report.

4.0 PT Review

Geo Labs participates in a number of external certification and PT programs, including the US Army Corps of Engineers (USACE) laboratory evaluation program, and Environmental Protection Agency (EPA) WP/WS proficiency sample program. The laboratory also participates in the EPA Contract Laboratory Program (CLP) for Inorganics. A list of the external

evaluations in which the laboratory participates in, is provided in Appendix D. The laboratory has successfully analyzed all PT samples processed within the past two years.

PT samples reflective of the Navy standard suite (i.e., VOC/8260/water, BNA/8270/water & soil, Pest/8081/water, PCBs/8082/water & soil, Metals (23 Metals)/6010/7000 series/water & soil) were ordered by ABC Auditor, Inc., and generated and scored by TestCo. The PT samples were received by the laboratory on 02 Feb 98, and the results were due on or before 3 Mar 98. Geo Labs processed the sample and submitted the results to TestCo on 25 Feb 98, copies of all sample summary data sheets are provided as Appendix E. Geo Labs also generated a data package for the PT sample. The data package was received by the assessors on 10 Mar 98. Deficiencies associated with the data package are provided in Section 6.8. The results of PT analysis were received from TestCo on 12 Mar 98, a copy is provided as Appendix F. The laboratory passed all PT samples.

5.0 On-Site Assessment

The following information is presented in association with the on-site assessment performed by ABC Auditors Inc., of Geo Labs – Los Angeles, California, from 01 through 03 Apr 98.

5.1 Scope and Objective

The scope of the assessment included an assessment of the laboratory's capability to perform CLP and SW-846 methods. The objective of the on-site assessment of the Geo Labs laboratory was to determine whether the laboratory's quality assurance (QA) program and QC practices meet the requirements of the Navy's IR QA Program and are consistent with good laboratory practices.

5.2 Evaluation Criteria

The on-site assessment of the laboratory was based on the Navy's IR QA program requirements as defined in the *Navy Installation Restoration Chemical Data Quality Manual,* dated Jun 98.

EPA's Test Methods for Evaluating Solid Waste SW-846, EPA Contract Laboratory Program Statement of Work, Exhibit F for evidentiary requirements and the Geo Labs Quality Assurance Plan dated 7 Jun 93(for internal requirements), and SOPs were also used as performance standards.

5.3 Description

Upon arrival at the laboratory, the assessors held an orientation meeting with management, QA, and technical personnel, during which the elements of the Navy's IR laboratory assessment program were described. A summary of items discussed is presented as Appendix G, Opening Meeting Checklist.

Following a description of the scope and schedule for the assessment, the assessors adjourned the opening meeting, and initiated their review of laboratory operations. The assessment of Geo Labs addressed all aspects of routine laboratory operations, including:

- sample management
- data handling
- quality control (QC) practices
- record-keeping
- training
- sample preparation
- organic, inorganic, and classical analysis sections

The adequacy of the laboratory's QA program was assessed. The facility, instrumentation, documentation, and support practices were reviewed. Spot checks were performed on standard operating procedures (SOPs). The assessors interviewed the QA manager, information systems manager, section managers, analysts, technicians, and support personnel. A list of areas reviewed is provided as Appendix H. At the conclusion of each day, the assessors met with the QA manager, laboratory manager, company vice-presidents, and section managers to provide a summary debrief of the day's deficiencies and observations.

At the conclusion of the assessment, the assessors conducted an exit brief with laboratory management, the QA manager, and technical personnel. During the brief the assessors presented verbal review of deficiencies and observations identified during the course of the on-site assessment, and the laboratory was supplied with a written summary deficiencies and observations. This summary is the basis of deficiencies and observations presented in Section 6.0. The lead assessor verbally presented the actions that would be taken upon conclusion of the on-site assessment. Laboratory personnel asked questions as needed throughout the exit brief. A summary of items discussed is presented in Appendix G, Exit Brief Checklist.

Attendee lists for meetings held are provided in Appendix I.

6.0 Deficiencies

During the course of the assessment, assessors noted policies, practices, documents, or records that did not comply with evaluation criteria identified in Section 5.2. Deficiencies must be resolved in order to comply with Navy IR QA Program requirements. Detailed information regarding the corrective action process is identified in the Navy IR CDQM, Appendix B, Section X.XX. Checklists that document deficiencies and observations are provided in Appendix G, Laboratory Operations Checklist, and Method Review Checklist.

6.1 Geo Labs' QA manager also has project management responsibilities. This practice is not compliant with Navy policy.
(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.XX)

6.2 The QA manager spends approximately 10 hours per week on QA activities. This amount of time is insufficient for a laboratory of Geo Labs' size, as reflected by the deficiencies associated with the laboratory's QA program (see Section 6.3 of this report).
(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1 Section X.X).

6.3 Laboratory QA program deficiencies were identified in the following areas:

- Corrective Action System: Procedures for the corrective action to be taken when testing discrepancies are detected, are not documented, or implemented.
  Examples include:
  - For cyanide determination, two sequential out-of-control situations were recorded on the control chart. There was no documentation available to indicate if and what corrective actions were implemented.
  - Corrective action related to transcription errors that resulted in order of magnitude errors on WP samples were not documented.

  (Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.XX , Item S).

- Internal Assessments: An internal assessment of the QA system has not been performed within the past 12 months.
  (Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.X)

- Documentation:
  - QA Manual: Although the QA manual is well written, it has not been updated since 1993, and is not reflective of current practices. Specific QA manual deficiencies include:
    - Job descriptions of key staff are not included
    - Corrective action policies and procedures are not clearly defined
    - Procedures for dealing with complaints is absent
    - QC checks seem to be biased toward the requirements of organic analyses, and contain very vague descriptions of metals and inorganic analyses.

(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.X and X.XX)

- SOPs are not controlled documents.
  (Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.XX)

- Test Conditions: There are no measures in place to assure constant and consistent test conditions (e.g., temperature, humidity, light, or specific instrument conditions).
  (Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.XX, Item H)

6.4 Method Deviations:

6.4.1 Method 9010: Cyanide calibration is performed with five calibration levels and a blank. The method requires six levels and a blank.
(Requirement Reference Method 9010, Section X.X)

6.4.2 Method detection limit (MDL) studies were not performed for solids for organic methods.
(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.XX)

6.4.3 Method 6010: The continuing claibration verification (CCV) standard is not being run every ten samples.
(Requirement reference: Method 6010, Section X.X.X).

6.5 Equipment:

6.5.1 The thermometer used to determine temperature during TCLP extraction is not certified or monitored.
(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.XX).

6.5.2 The laboratory does not have the equipment required to run volatile solid samples. The laboratory is currently running volatile solid samples, however, they do not have heated purge capability.
(Requirement reference: Method 5030A Section X.X.X and X.X.X.X)

6.6 Record Keeping: Corrections in log books and on bench sheets are not always initialed and dated and unused lines are not always "Z'd" through.
(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.X.XX)

6.7 Personnel:

6.7.1 Continuing demonstration of method performance (i.e., successful completion of a PT sample within the past 12 months) has not been initiated for the following analysts/analysis:

- Joe Smith/Mercury
- Amy Martinez/Cyanide

(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.X.XX).

6.7.2 There is no SOP that defines Geo Labs' training and qualification requirements. (Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.X.XX)

6.8 Data Package: The data package received (by ABC Auditors Inc., on 10 Mar 98) was reviewed for conformance with Navy requirements. The data package, identified as Geo Labs job number 1055, was a compilation of results generated from the PT sample ordered by ABC Auditors Inc. The data package did not include sufficient information for accurate interpretation. Including:

- Discussion of all re-analyses and dilutions References to methods and revisions was not provided
- A statement of estimated uncertainty was not included
- TIC data was not reported
- Second column analytes were not reported
- Method 8260:
  - Run log was not provided
  - Tune data was not summarized
- Method 8021
  - LCS outliers were not addressed
  - An ending calibration was not performed
  - Spiking levels were not documented for LCS or surrogates

(Requirement reference: Navy IR CDQM, Appendix C, Enclosure 1, Section X.X.XX).

7.0 Observations

This section presents general observations which reflect on the capabilities and capacity of the laboratory. Response from the laboratory is not required.

7.1 The laboratory’s facility provides ample space for production analytical work and support activities, with appropriate segregation of functional areas.

7.2 The laboratory does not routinely perform volatile low-level soil analysis.

8.0 Conclusions

Geo Labs has the staff, facilities, equipment, and infrastructure necessary to provide Navy IR projects with environmental analytical services. However, the laboratory QA program is inadequate to support the size and complexity of the laboratory and is the cause of many failures to meet Navy IR QA requirements. The staff members are generally qualified for their positions and have relatively long associations with the laboratory.

Geo Labs has been advised to respond in writing to the assessment deficiencies in this report within 14 calendar days of receipt of this report. For each deficiency (and each individual "bullet"), the response must address the laboratory's plan of action and completion schedule for implementation of corrective actions. All corrective actions must be completed, with supporting documentation received by ABC Auditors Inc., within 60 calendar days of receipt of this report. Laboratory management may request an extension of up to 21 calendar days by providing rationale for why an extension is needed. In addition, if the laboratory takes exception to any of the deficiencies in this report, the laboratory's response must identify and provide an explanation for the exception(s). Detailed information regarding extensions is found in Navy IR CDQM, Appendix B, Section X.X.XX, and information regarding exceptions is found in Section X.XX.

APPENDICES:

Appendix A: Floor Plan of the Laboratory
Appendix B: List of Current SOPs
Appendix C: List of Instrumentation
Appendix D: List of Current Status for External Evaluations
Appendix E: Sample Summary Data Sheets
Appendix F: PT Sample Results
Appendix G: Assessment Checklists
- Opening Meeting
- Laboratory Operations
- Method Reviews
- Exit Brief

Appendix H List of Areas Reviewed
Appendix I Attendees Lists
- Opening Meeting
- Exit Brief

Appendix B
Attachment 6
Laboratory Proposal Package
Checklist

Laboratory Proposal Package Checklist

The following is a checklist of the documents (original documents or certified copies) that must be included in the proposal package forwarded by the Contractor (or NFESC) to the EFD/EFA when the laboratory is proposed for use.

- ❑ Initial Laboratory Assessment Package
- ❑ Initial Assessment Recommendation Letter
- ❑ Current Proficiency Testing Documents
- ❑ On-site Assessment Report
- ❑ Laboratory Corrective Action Plan
- ❑ Assessment of Planned Corrective Actions
- ❑ Documentation of Corrective Actions Implementation
- ❑ Request for Extension of Corrective Action Documentation (if applicable)
- ❑ Follow-Up Assessment Documentation (if applicable)
- ❑ Assessment Recommendation Letter